Principles of Laboratory Biosecurity – Worksheets for Small Group Exercises

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This is an exercise designed to familiarize workshop participants with the major concepts employed in assessing the risk of theft of biological materials from bioscience facilities. The methodology described in this exercise has been extremely simplified and does not represent the actual methodology employed by Sandia National Laboratories, but is instead a generalized example of the issues involved.

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Biological Agent Consequence Worksheet

Step 1: Identify one or more biological agents in your facility (or a fictitious facility), that may be attractive to an adversary with malicious intent and evaluate the consequences of loss (i.e. the population, economic, and psychological impacts that may result from the agent's use as a weapon). Please use the chart on pg 4 to assign scores (0 – 4). Non-integer values can be used if you think that the agent does not fall into one of the defined categories.

Biological Agents	Population Impact	Economic Impact	Psychological Impact	Average Consequence Score
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				

Asset Consequence Assessment

Consequence Criteria	Values				
	Very High (4)	**High (3)**	**Moderate (2)**	**Low (1)**	**Very Low (0)**
Population Impact	The agent has a high rate of morbidity (50-100%) that would most likely require hospitalization and / or resulting disease is almost uniformly fatal (expected unvaccinated and untreated mortality > 90%).	The agent has a high rate of morbidity (50 – 100%) that would most likely require outpatient treatment and / or resulting disease has high fatality rate (expected unvaccinated and untreated mortality 50% to 90%).	The agent has a low rate (0 to 50%) of morbidity but would most likely require hospitalization and / or resulting disease has moderate fatality rate (expected unvaccinated and untreated mortality 15% to 50%).	The agent has a low rate (0 to 50%) of morbidity that would most likely require outpatient treatment and / or resulting disease has low fatality rate (expected unvaccinated and untreated mortality 1% to 15%).	The agent has a low rate (0 to 50%) of morbidity but would not be likely to require any treatment and / or resulting disease does not typically result in fatalities in healthy adults (expected unvaccinated and untreated mortality of <1%).
Economic Impact	Major global and national impact on financial markets and international trade. Significant increase in the cost of business causing many industries extreme financial hardship. Immediate government intervention required to stabilize the economy. Substantial cost associated with recovery.	Moderate fluctuation in financial markets and/or international trade. Moderate increase in the cost of business. Economy may require government intervention to recover.	Small fluctuation in financial markets and/or international trade. Minor ongoing increase in the cost of business. Economy able to rebound and recoup losses within weeks.	No fluctuation in financial markets or international trade. Minor financial impact associated with recovery. Economy able to rebound and recoup losses within days.	Insignificant economic impact
Psychological Impact	An attack would have an extreme impact: Mass public panic with extreme social disruption (elements of public infrastructure cease to function); significant threat to national security.	An attack would have a high impact: Mass public panic with significant social disruption but continuation of essential societal functions (widespread closures of public infrastructure, such as schools, regional transportation networks, some government services halted); moderate threat to national security.	An attack would have a moderate impact: Significant public anxiety with minimal social disruption (small scale closures of public infrastructure, such as schools, local transportation systems, and government offices).	An attack would have a low impact: scattered public anxiety; no social disruption.	An attack would have no significant impact on the behavior of the public.

Biological Agent Weaponization Worksheet

Step 2: Risk is a function of likelihood and consequences. It is difficult to assess the likelihood of a malicious event; thus, we will use the relative ease of acquiring, producing, and disseminating an agent ("weaponization potential") as a proxy for likelihood. Evaluate the weaponization potential (i.e. acquisition, production, and dissemination issues that may impact the agent's use as a weapon). Please use the chart on pg 6 to assign scores (0 – 4). Non-integer values can be used if you think that the agent does not fall into one of the defined categories.

Biological Agents	Acquisition	Production	Dissemination	Average Weaponization Score
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				

Weaponization Potential Assessment

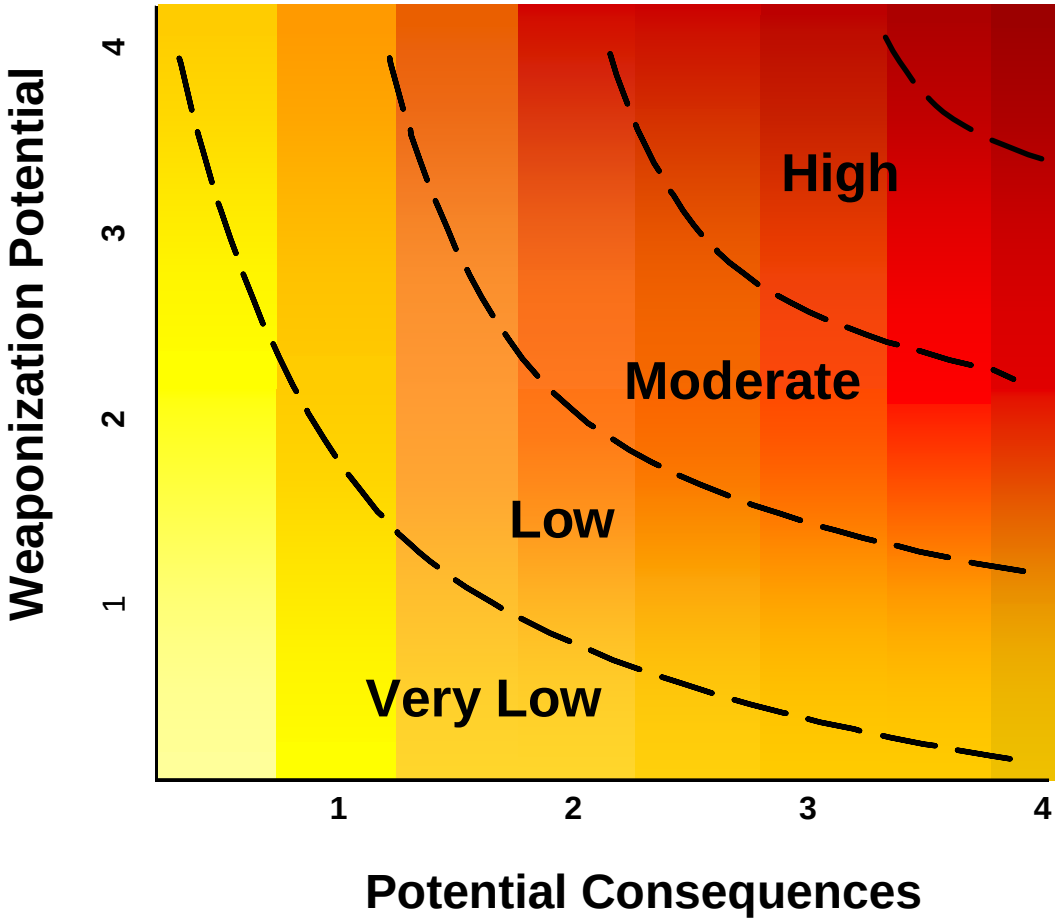
Weaponization Criteria	Values			
	Very High (4)	**High (3)**	**Moderate (2)**	**Low (1)**
Acquisition	The facility is one of only a few locations (<5) for obtaining the agent (e.g. smallpox, a novel genetically engineered agent).	The facility is one of only a few locations (< 25) for obtaining the agent; the natural reservoir is unknown, and outbreaks are rare.	There are many facilities that possess the agent but restrictions exist; the agent is endemic to a few, distant areas.	The agent is nearly ubiquitous (found in facilities throughout the world and endemic in many areas of the world).
Production	The agent requires no testing to use reliably. Production requires no special methods and/or protocols for safe handling to avoid detection. Storage of this agent in a dry formulation is straightforward (e.g. known process and / or minimum lifetime of many months).	The agent requires minimal testing and evaluation prior to use. Production requires minimal technical capabilities and/or protocols for safe handling to avoid detection. Storage of this agent in a dry formulation is difficult (e.g. unknown process and / or limited lifetime).	The agent requires moderate testing and evaluation prior to use. Production requires general technical capabilities and/or protocols for safe handling to avoid detection. Storage of this agent in a liquid formulation is straightforward (e.g. known process and / or minimum lifetime of many months).	The agent requires extensive testing and evaluation prior to use. Production requires advanced technical capabilities and/or sophisticated protocols for safe handling to avoid detection. Storage of this agent in a liquid formulation is difficult (e.g. unknown process and / or limited lifetime).
Dissemination	The agent has or is assumed to have an extremely high infectivity or toxicity via inhalation. (ID_{50} or LD_{50} <100; Toxin LD50 <0.1 µg/70 kg), the agent has a very high aerosol stability (temperature, humidity, UV).	The agent has or is assumed to have a high infectivity or toxicity via inhalation. (ID_{50} or LD_{50} 100-1000; Toxin LD_{50} 0.1 -100 µg/70 kg); the agent has a high aerosol stability (temperature, humidity, UV).	The agent has or is assumed to have a moderate infectivity or toxicity via inhalation. (ID_{50} or LD_{50} 1,000 – 50,000; Toxin LD_{50} 100-5000 µg/70 kg), the agent has a moderate aerosol stability (temperature, humidity, UV).	The agent has or is assumed to have a low infectivity or toxicity via inhalation. (ID_{50} or LD_{50} > 50,000; Toxin LD_{50} > 5000 µg/70kg), the agent has a low aerosol stability (temperature, humidity, UV).

Agent Risk Assessment Worksheet

Step 3: Transfer the average consequence and average weaponization scores to this chart. Plot your results on the graph and assign risk groups to the agents.

Agent	**Average Consequence Score**	**Average Weaponization Score**	**Risk Group – EMUR, HMUR, MMUR, LMUR** (to be completed based on graph on next page)
1.			
2.			
3.			
4.			
5.			
6.			
7.			

Graph: Agent Risk



Descriptions of the agent risk groups can be found on the following page.

Agent Risk Group Descriptions

Nonpathogenic: The inherent hazards of the agent would result in no or insignificant consequences if used maliciously.

Low Malicious Use Risk (LMUR): Pathogens and toxins that are difficult to deploy maliciously, and/or the inherent hazards of the agent would result in low consequences if used maliciously.

Moderate Malicious Use Risk (MMUR): These pathogens and toxins are relatively difficult to deploy as a weapon and the inherent hazards of the agent could have localized consequences, causing low to moderate casualties or low to moderate economic impacts, and potentially cause pervasive anxiety if used maliciously.

High Malicious Use Risk (HMUR): These pathogens and toxins are not particularly difficult to deploy as a weapon and the inherent hazards of the agent could have national or international consequences, causing moderate to high casualties or moderate to high economic impacts, and have the potential to cause mass panic and significant social disruption if used maliciously.

Extreme Malicious Use Risk (EMUR): These pathogens and toxins would normally be classified as HMUR, except for the fact that they are not found in nature. This could include either eradicated or genetically engineered agents, if the agent would otherwise be classified as HMUR.

Step 4: Describe how the agents are used in the laboratory and consider whether the laboratory activity with the agent increases the level of risk.

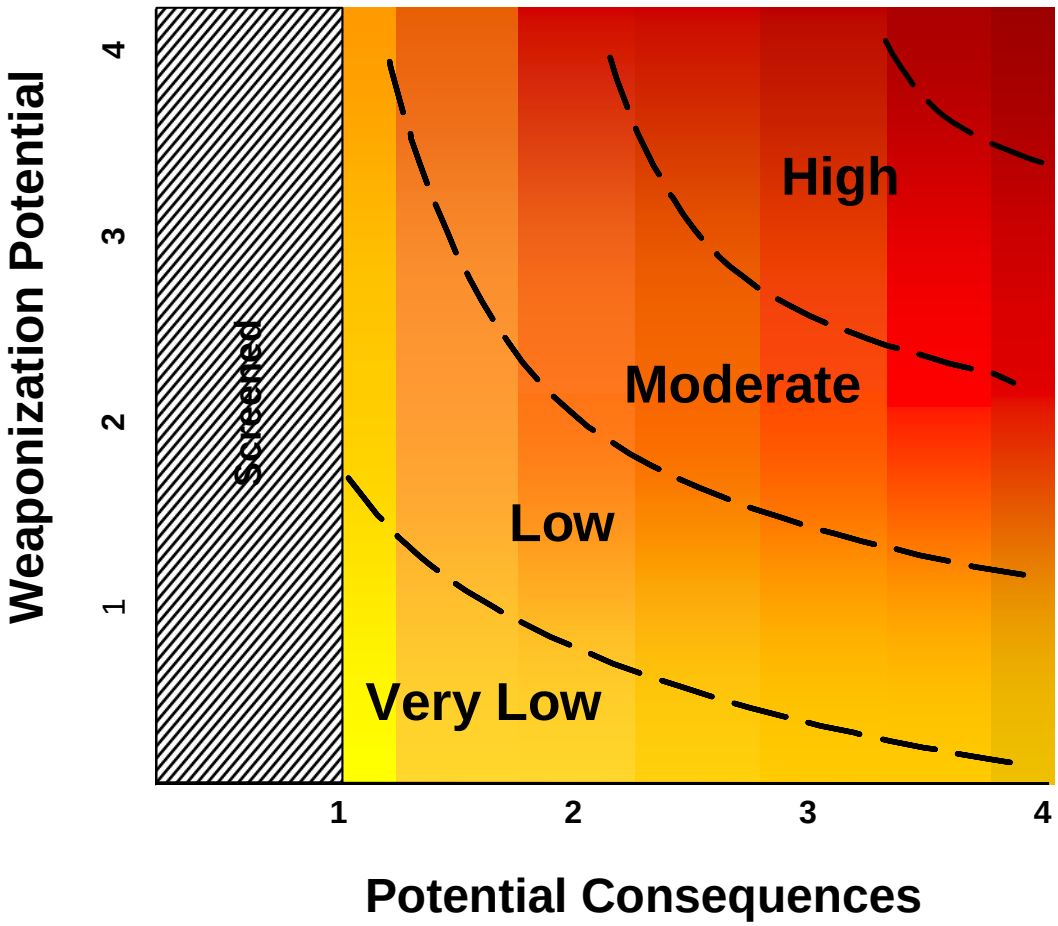
1. Does the lab activity modify the consequences (e.g. drug resistance)?

2. Does the lab activity modify the weaponization potential (e.g. large quantities of respirable particles)?

If your lab activity modifies the risk, explain why. Update the graph on pg 11 to reflect these risk modifiers. Refer to pgs 4, and 6 – 7 as a guide.

Step 5: Update graph to reflect lab activities.

Graph: Agent Risk – modified by Lab activity



Agent Risk Modified by Lab Activity Summary and Screening Worksheet

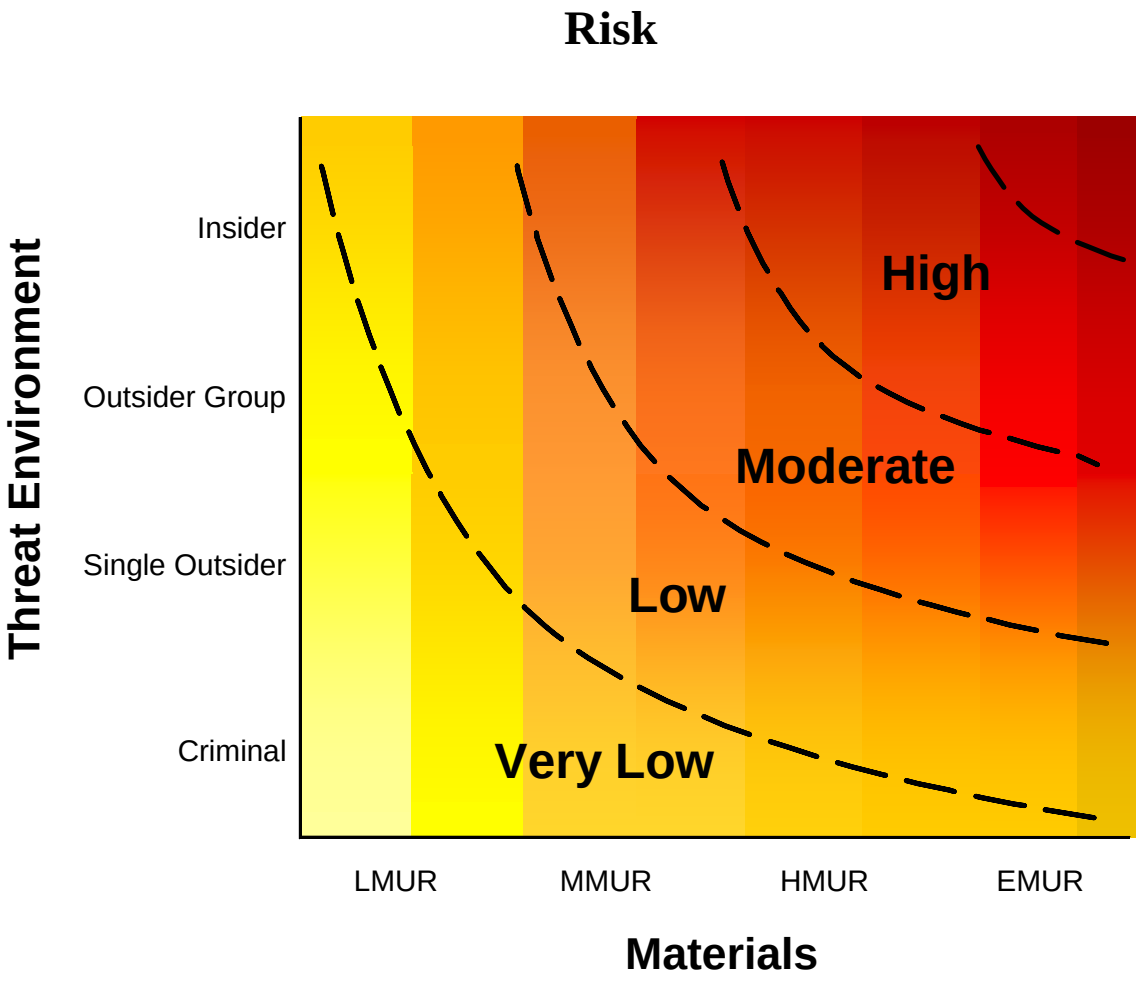
Step 6: Transfer the average consequence and average weaponization potential scores from the agent risk modified by lab activity graph (pg 11) to this chart. Re-assign risk groups to the agents.

Agent	Average Consequence Score	Average Weaponization Score	Risk Group – EMUR, HMUR, MMUR, LMUR
1.			
2.			
3.			
4.			
5.			
6.			
7.			

Since resources are always limited, we will assume that the facility will not want to provide security for biological agents with low potential consequences. Screen the lowest consequence biological agents from the analysis by drawing a line through those with an average consequence score less than or equal to 1. This will allow us to simplify the risk assessment by limiting the number of agents on which we conduct a full analysis.

Threat Environment

Step 7: Consider the descriptions of the different classes of notional adversary described on pgs 14 – 15. Discuss with your group whether you agree with the assumptions and conclusions reflected in the risk graph below.



Notional Adversary Capability

For the purposes of this exercise we have provided notional adversary profiles and capabilities.

An adversary's capability is evaluated, within the context of the threat he poses to biofacilities holding dangerous biological materials, based upon his ability to acquire, develop, and use biological material as a biological weapon. In order to acquire the material from a facility, the adversary must have access to the materials, or the ability to acquire the materials by stealth or through forceful means.

If an adversary is an outsider he has the disadvantage of limited operational knowledge—where the materials are stored and how they are differentiated, what security and safety measures are in place, etc. Some of the information may be directly observable or stolen electronically, depending on the skill of the adversary and how well protected the institution's information is; the more direct knowledge the adversary is able to obtain, the greater the threat he will pose. The outsider may need to overcome physical barriers, including personnel who may attempt to interfere, in order to acquire the biological agent.

The likelihood that outsider may accomplish an overt attack and successfully steal a biological agent without being apprehended will depend on the types of tools and weaponry he has, his level of assault training, and the level of security at the facility. The ability to develop and deploy biological materials as a weapon will be influenced by the adversary's scientific skill set; ability to acquire and use appropriate production equipment; ability to establish a safe working environment; access to financial resources; and ability to acquire and utilize dissemination equipment effectively.

1. **Skilled insider with full access to the targeted biological agent -** This may be a laboratory scientist who has authorized access to the asset being evaluated. He/she has scientific knowledge and authorized access. Authorized access affords this person extensive knowledge of the facility and operating systems. This insider would be expected to abort any theft attempt to avoid identification, and is not skilled or equipped to break through anything beyond nominal security barriers (e.g. may be able to open a locked door using a credit card or pin). This insider is non-violent. This insider has the opportunity to choose the best time to commit a malevolent act.

2. **Outsider Group -** Terrorist groups are usually well funded and may be supported by member states, religious groups, or even organized crime. Funding provides this adversary the opportunity to be well equipped, trained, and able to rehearse the attack. They may be violent and willing to die. Terrorist groups may have members with scientific skills or have access to those who do, but the level of skill for this terrorist group is lower than that of the facility scientists working directly with specific biological material. This terrorist group has limited access to facility information; they only know what is directly observable from publicly accessible areas and what is published in publicly available forums (e.g. the

institution's web site). This terrorist group is well armed with firearms and explosives, as well as other tools useful for overcoming security barriers.

3. **Single Outsider** – Individuals have fewer resources (financial, logistical, and personnel) than well-developed terrorist groups. This single outsider is well trained in assault tactics, well armed (but somewhat less so than the terrorist group), and is violent and willing to die. This single outsider has basic biology skills, but no advanced training. He/she only has access to that information about the facility that is publicly available.

4. **Criminal** – The motivation of the criminal is financial gain. He/she may use weapons and hand tools. The criminal's tactics include theft or damage/destruction to harm a competitor. In extreme cases, he/she are affiliated with organized crime.

Site Evaluation

Step 8: Evaluate your site.

Note: Local law enforcement should be consulted for the evaluation of site environment and may also be helpful in evaluating the current facility security.

a. Work environment: Does your facility have healthy labor relations, good management, state of the art equipment and facilities, excellent opportunities for job growth, generous compensation?

b. Site environment: Does your facility conduct work of a controversial nature? Is there a history of terrorism, political instability, extremist or criminal activity in your area? Is the facility located in a high density area? Are the areas for storage and use of dangerous biological agents on the perimeter? Does your facility have a public service function (i.e. does the public make on site calls for service?)? Is there any indication of the facility being a possible target?

c. Current security: Does your facility have a risk-based, graded, biosecurity system (including appropriate physical security, personnel security, material handling and control, transportation security, and information security)? Is it operating properly?

Step 9: Discuss how your site evaluation alters the risk for your facility. Would any of the scenarios (in Step 8, p 13) increase or decrease in risk?

Designing a Biosecurity Program

Step 10: Decide which biosecurity scenarios your facility should protect against. Then outline a biosecurity program for your facility based on that risk management decision.

Physical Security:

Personnel Security:

Material Control & Accountability:

Transfer Security:

Information Security:

Program Management:

Protection Principles

To protect against the insider threat

- Scientific program oversight
- Personnel security program
- Information system security
- Material control and accountability
- Chain-of-custody procedures for regulated agents in intra-facility transit
- Access controls
- Alarm assessment and response capability

To protect against the outsider threat

- Visitor screening and escort procedures
- Information system security
- Material control and accountability
- Intrusion detection and access controls
- Alarm assessment and response capability
- Chain-of-custody procedures for regulated agents in inter-facility transit